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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/210,031	12/11/1998	ATTILA T. LORINCZ	2629-4005US1	6182

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MORGAN & FINNEGAN
345 PARK AVENUE
NEW YORK, NY 10154

EXAMINER
BRUSCA, JOHN S

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/210,031	Applicant(s) LORINCZ ET AL.	
	Examiner Brusca S John	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on *18 January 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *36-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) *36-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Declaration by Dr. Attila T. Lorincz accompanying the Response received 18 January 2002 has been reviewed and entered into the instant application. The prior filed copy of the Declaration apparently was lost through Office error. The Office apologizes for any inconvenience this may have caused the Applicants.

Claim Objections

2. Claims 36-54 are objected to because of the following informalities: claims 36-54 recite in independent claims 36 and 37 the phrase "A cell or tissue collection medium, wherein the cells or tissue contained in the medium can be analyzed directly by both cytological and molecular methods" because the claims are drawn to tissue collection medium rather than tissue collection medium comprising cells or tissue.

Claim Rejections - 35 USC § 103

3. Claims 36-48, 51-54, 58, 59, and 61 are rejected under 35 U.S.C.§103(a) as being unpatentable over Dunphy et al. for reasons of record in the Office action mailed 23 October 2001.

4. Claims 49, 55-57, 60, and 68-74 are rejected under 35 U.S.C.§103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Weber in view of Harrison for reasons of record in the Office action mailed 23 October 2001.

5. Claims 62-66 are rejected under 35 U.S.C. §103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 above, and further in view of Wainwright for reasons of record in the Office action mailed 23 October 2001.

6. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dunphy as applied to claims 36-48, 51-54, 58, 59, and 61 and further in view of Wainwright above, and further in view of Weber in view of Harrison for reasons of record in the Office action mailed 23 October 2001.

7. Applicant's arguments filed 18 January 2002 have been fully considered but they are not persuasive. The Applicants argue that Dunphy shows a medium useful for histology, and that histology is not concerned with molecular testing. However histology includes methods that specifically detect molecules, for example molecules that bind a certain stain are detected by histological stains. Molecular analysis such as in situ hybridization is shown by Weber et al. to be useful for analysis of tissue for pathological assays. The Applicants state that Dunphy does not provide motivation to add EDTA to the medium number 4 of Dunphy, however Dunphy provides general guidance that EDTA can be added to media to retard growth of bacteria, and therefore the addition of EDTA to tissue preservation media is obvious. Dunphy does not teach away from addition of EDTA to medium number 4 of Dunphy, contrary to the Applicant's assertion. The Applicants assert that Weber et al. and Harrison are from divergent arts, however both Weber et al. and Harrison discuss use of tissue collection medium comprising aldehydes for treating tissue for subsequent use in detection of particular molecules. The Applicants attempt to create contradictory teachings among the cited references regarding the type of aldehyde to be used, however Dunphy shows in Example 4 a tissue collection medium comprising ethanedial, Weber et al. shows on page 8 that their tissue collection medium should contain the general class of "cross linking fixatives (such as aldehydes)", and Harrison shows in column 3 that glutaraldehyde may be used as a fixative. Therefore all references are consistent in suggesting

addition of aldehydes to a tissue collection medium. The Applicants appear to incorrectly characterize Dunphy as prior art that is exclusively concerned with mortuary science, however Dunphy specifically states that the medium 4 of Dunphy is useful for preparing tissue samples for histological study. The Applicants state that the applied references do not show sequential morphological and molecular analysis of tissue samples, however Weber et al. teaches such analysis at least on page 4, and Harrison shows in column 3 to add desired dyes or stains in addition to antigen specific reagents.

Double Patenting

8. Claims 36-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-41, 46-55, 60-66, 71-75, and 80 of copending Application No. 09/598571 in view of Weber et al. (WO 94/02645, cited in the Form PTO 1449 received 07 June 1999) in view of Harrison for reasons of record in the Office action mailed 23 October 2001.

9. Applicant's arguments received 18 January 2002 have been fully considered but they are not persuasive. The Applicants state that the rejection is premature, however MPEP 804 states Office policy on this matter as follows:

> Occasionally, the examiner becomes aware of two copending applications filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott,* 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau,* 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue. The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the "provisional" double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday -Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-5137 for regular communications and (703) 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

John S. Brusca, Ph.D.
Primary Examiner
Art Unit 1631

jsb
April 2, 2002